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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: ALVAREZ,Vernon, *et al.* Examiner: LUKTON, David
Serial No: 10/522,810 Group Art Unit: 1654
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Corresp. to: PCT/US03/17411
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Title: TREATMENT of CELL PROLIFERATIVE DISORDERS WITH CHLOROTOXIN

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Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

RESPONSE TO ELECTION REQUIREMENT

Responsive to the new Restriction Requirement mailed October 7, 2008 in the above-referenced case, which is the fourth Restriction Requirement in the case (the “Fourth Restriction Requirement”), Applicant offers the following remarks, intended to clarify the record in the case.

Confirmation and Correction of Previously Elected Subject Matter

As an initial matter, Applicant confirms the prior election, with traverse, of group 14 (subgenus G1), claims 42-49.

Applicant also thanks the Examiner for pointing out that Applicant inadvertently selected SEQ ID NO:10 (TDHQMARKS), rather than SEQ ID NO:13 (TTDHQMARKS) for initial prosecution. Applicant hereby elects SEQ ID NO:13 for initial examination.

Applicant also thanks the Examiner for confirming that (1) the elected claims do encompass both therapeutic and diagnostic methods (although initial examination will

exclude those methods), and (2) that it would be appropriate to “rejoin”¹ at least therapeutic methods if the initial examination confirms patentability of the elected claims.

Restriction vs Unity of Invention

Applicant wishes to clarify the record with respect to the question of whether restriction or unity of invention practice is proper in the present case. The Fourth Restriction Requirement contains several statements purporting to characterize Applicant’s position and representations that do not in fact represent Applicant’s remarks.

For clarity, Applicant’s position is simply that, as set forth in 37 C.F.R. §§ 1.475 and 1.499, unity of invention practice, not restriction practice, applies in the instant application. The Patent and Trademark Office has set forth different standards for claim examination under restriction practice as compared with unity of invention practice and, as explained in the prior Response (i.e., the Response to the third Restriction Requirement in this case), it is Applicant’s position that the claims as written are linked by a unifying inventive concept, that is, methods using polypeptides comprising chlorotoxin subunits having sequences as defined in claim 42. It is this position that supports Applicant’s traverse of the Restriction Requirement.

To the extent that the Fourth Restriction Requirement includes any statement characterizing Applicant’s position that is different from what is said above, Applicant rejects the characterization.

For example, the Fourth Restriction Requirement states “Applicants have traversed the restriction requirement by arguing that merely by paying the fee for a PCT application, applicants subsequently enjoy blanket ‘immunity’ from restriction, no matter how many different inventions they have managed to group together in a single claim”. Of course, this statement badly mischaracterizes Applicant’s position. Applicant simply has pointed out that different legal standards have been implemented for different classes of cases. As noted above, in responding to the third Restriction Requirement, Applicant carefully analyzed the unity of invention standard, and explained why it is satisfied by the

¹ Applicant understands the concept of “rejoinder” as typically applied to sets of claims, and is a bit unclear with respect to its application in this case, which would involve “rejoinder” of *subject matter* already within a claim. Regardless, Applicant understands that the Examiner will first examine the pending claims as they relate to non-therapeutic and non-diagnostic methods. If allowable subject matter is found, the Examiner will extend his consideration to at least therapeutic methods.

present claims.

The Examiner has also invited Applicant “to make the following admissions on the record . . .”. The “admissions” requested by the Examiner are not part of the unity of invention standard and are not invoked merely by pointing out that unity of invention is the proper standard. As the Examiner himself points out, unity of invention requires a “special technical feature” that define a contribution over the prior art. The present claims share such a special technical feature; nothing more is required and Applicant makes no further representation, “admission” or otherwise.

Response to New Restriction/Election Requirement

The Fourth Restriction Requirement levies yet another layer of restriction or election requirement. It is not clear which the Examiner intends because he references a requirement “under 35 USC §121 to elect species/subgenera”. The term “species” implies election, but the Examiner has previously been emphatic that he applies restriction requirements to “subgenera”. Assuming that all claims will be examined to their full scope should the initial examination find patentable subject matter, Applicant hereby elects the following for initial examination:

- j) prostate cancer cells as a specific type of cancer cell;
- k) cancer cell proliferation is not augmented (Applicant notes that the Examiner’s choices were inhibited or augmented, but in fact neither is required by, or recited in, the present claims; Applicant has therefore elected a claim scope in which cancer cell proliferation is not augmented, which encompasses binding that either inhibits or does not affect proliferation);
- l) absence of a second agent
- m) polypeptide contains 10 amino acids or fewer
- n) polypeptide has an amino acid sequence that comprises SEQ ID NO:13.

Applicant respectfully invites the Examiner to begin substantive examination of this case, and looks forward to the results.

As already addressed, Applicant also reserves the right to pursue claims to non-elected species and subgenera as prosecution develops.

Please charge any necessary fees or credit any overpayments to our Deposit Account No. 03-1721.

Respectfully submitted,

Dated: October 7, 2008

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